

REMARKS

Claim 51 has been amended to recite that the first and second reagents form first and second reaction products when "contacted with a mixture of the sample and the labeled indicator reagent to produce a corresponding detectable response" in each of the test and reference zones, respectively. Claim 51 has also been amended to replace the phrase "reaction zone" with "reference zone" in the second wherein clause. Support for these amendments can be found in the specification at, for example, page 8, line 2 - page 12, line 15; page 13, lines 1-18; page 21, line 20 - page 41, line 25 - page 43, line 12; and page 46, line 18 - page 47, line 26; and in Examples 3-9.

35 U.S.C. § 112, ¶ 2

Claims 51-56 have been rejected as indefinite. (Paper No. 20071127 at 2.) In regard to claim 51, it is the view of the Patent Office that "claim 51 is vague with respect to the recitation in part (b) [because] . . . [i]t is unclear what this [first] reagent is that can bind to the 'sample' and produce a response that is inversely proportional to the analyte. If the reagent binds to a 'sample', doesn't it produce a response that is proportional?" (*Id.* at 2-3.) The Examiner observes that "[r]esponses that are inversely proportional normally involve reagents that compete with the sample analyte for binding to a labeled analog of the analyte." (*Id.*)

In addition, the Examiner determined that "the recitation of 'the reaction zone' in the second 'wherein' clause lacks antecedent support." (*Id.*) Applicants respectfully traverse.

To reject a claim under the second paragraph of 35 U.S.C 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have

been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. *Ex parte Wu*, 10 U.S.P.Q.2d 2031, 2033 (BAY 1989). This, the Examiner has not done. The rejection contains no factual determination that establishes that one of ordinary skill in the art "would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims" based upon the recitation of claim 51.

As discussed above, claim 51 has been amended to recite "at least one test zone having non-diffusively bound thereto a first reagent that forms a first reaction product when contacted with a mixture of the sample and the labeled indicator reagent mixture to produce a corresponding detectable response in the test zone, the detectable response being inversely proportional to the analyte concentration." Thus, claim 51 makes clear that is a mixture of the sample and the labeled indicator reagent that is contacted with the first reagent in the test zone.

Moreover, as the specification makes clear, the claimed assay device employs a competitive type configuration or an inhibition type configuration to produce the claimed inversely proportional response in the test zone. (See page 21, line 20 - page 24, line 22 and page 38, line 9 - page 48, line 10.) As one of ordinary skill in the art would recognize, such assay configurations would produce the claimed inversely proportional response in the test zone.

In the competitive type assay configuration the labeled indicator reagent is an labeled antigen. The first reagent (in the test zone) is an immobilized antibody capable of binding both the labeled antigen and the analyte. The analyte and the labeled antigen compete for the immobilized antibody. The response in the test zone is proportional to the amount of

labeled antigen bound to the immobilized antibody and therefore inversely proportional to the amount of analyte bound. (See page 21, line 20 - page 23, line 10.)

In the inhibition type assay configuration the labeled indicator reagent is a labeled antibody capable of binding the analyte. The first reagent (in the test zone) is an immobilized antigen capable of binding free labeled antibody. Thus, the free labeled antibody is bound by the immobilized antibody, but the labeled antibody bound by the analyte passes to the reference zone. The response in the test zone is proportional to the amount of free labeled antibody bound to the immobilized antigen and therefore inversely proportional to the amount of analyte in the sample. (See page 23, line 11 - page 24, line 22.)

In addition, claim 51 has been amended to replace the phrase "reaction zone" with "reference zone" in the second wherein clause. Accordingly, the phrase to which the examiner objects has been deleted.

For the foregoing reasons, it is submitted that one of ordinary skill in the art, when reading claim 51 (as amended) in light of the specification would readily recognize the particular area set out and circumscribed by the claims. Nothing more is required. Accordingly, the rejection of claim 51 has been rendered moot and withdrawal is requested.

With respect to claim 56, the Patent Office has determined that "[c]laim 56 is vague." (Paper No. 20071127 at 3.) In support of this rejection, the Examiner offers only questions: "Where are these reagents disposed on the porous member? In what zone? What is there function?" (*Id.*)

As discussed above, to reject a claim under the second paragraph of 35 U.S.C. 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification,

would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. *Wu*, 10 U.S.P.Q.2d at 2033.

The rejection of claim 56, however, consists of only a) the unsupported conclusion that "[c]laim 56 is vague" and b) three questions. (Paper No. 20071127 at 3.) Thus, the rejection completely fails to present the factual determination(s) required to support a rejection for indefiniteness. Simply put, the Patent Office has not demonstrated that one of ordinary skill in the art would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims.

Accordingly, the rejection fails to present a *prima facie* case for indefiniteness. For this reason alone, withdrawal of the rejection of claim 56 is requested.

Moreover, even if the Examiner had met the requisite factual burden, which is denied, the recitation of claim 51 read in light of the specification is definite. The claim recites various additional reagents that may be bound to the porous member. Clearly, such a recitation is definite on its face. The dependent claim recites exactly what is bound and where it is bound.

Moreover, the specification provides ample guidance to one of skill in the art to determine what is claimed. For example:

The layers of [the porous member] can contain any number of assay reagents including but not limited to buffers, salts, proteins, enzymes, and/or antibodies (either or both of which may be diffusively or non-diffusively bound to a particle or the bibulous material) polymers, small molecules, or any combination thereof.

(P.33 ll.16-21.)

The sample transport area can be untreated, or may have diffusively or non-diffusively immobilized therein on or more reagents such as stabilizing proteins, detergents, anticoagulants like heparin or EDTA, precipitating reagents, salts, proteins, enzymes, antibodies, enzyme-particle conjugates, antibody-particle conjugates, antigen-particle conjugates, red cell agglutinating agents like wheat germ lectin or anti-human RBC, polymers, and/or small molecules.

(P. 35 ll.15-22.)

Thus, it is submitted that one of ordinary skill in the art, when reading claim 56 in light of the specification would readily recognize the particular area set out and circumscribed by the claim. Nothing more is required.

For the forgoing reasons, the rejection of claim 56 fails to present a *prima facie* case for indefiniteness. Accordingly, withdrawal of the rejection of claim 56 is requested.

35 U.S.C. § 102(e)

Claims 51-60 have been rejected as anticipated by *Fitzpatrick et al.*, U.S. Patent 5,451,504 ("Fitzpatrick"). (Paper No. 20071127 at 3.) Applicants respectfully traverse this rejection.

Anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 45 F.3d 1550, 1554 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir 1984); *In re Marshall*, 578 F.2d 301, 304 (C.C.P.A. 1978).

Fitzpatrick discloses a membrane strip with three general zones: a mobilization zone, a trap zone, and a detection zone. (See Abstract; col. 1, lines 46-69; col. 2, lines 15-16; and col. 4, line 50 - col. 9, line 15.) In making the rejection, the examiner equates Fitzpatrick's mobilization

zone with the sample application zone of the invention, Fitzpatrick's trap zone with the test zone of the invention, and Fitzpatrick's detection zone with the reference zone of the invention. (See Paper No. 20071127 at 3-4.) The examiner characterizes the trap zone of Fitzpatrick as having "an immobilized ligand (that binds to the labeled reagent when analyte is not present producing a signal that is inversely proportional to the concentration of analyte) . . ." (Id. at 4.)

The instant claims require that a first reagent in the test zone that forms a first reaction product when contacted with a mixture of the sample and the labeled indicator reagent to produce a corresponding detectable response in the test zone, the detectable response being inversely proportional to the analyte concentration." Fitzpatrick, however, is silent as to any detectable response in its trap zone. In fact, this trap zone "comprises immobilized ligand that will bind, i.e., trap, free receptor moving through the trap zone, but will not bind receptor bound in a receptor-analyte complex." (col. 6, lines 39-41.)

In nearly two full columns of text devoted exclusively to the trap zone, Fitzpatrick says absolutely nothing about any detectable response, much less any inversely proportional response. In fact, Fitzpatrick specifically disavows any such inversely proportional response.

Fitzpatrick discloses only that the response in the detection zone has a positive correlation to the presence of the analyte. Fitzpatrick actually emphasizes the desirability of a simple signal that only detects a positive result.

Positive detection means that signal positively correlates with the presence of analyte in a sample. **A positive correlation is advantageous because it is psychologically satisfying that the presence of signal or increase in signal intensity indicates presence of**

analyte in a sample. Both sophisticated diagnostic laboratories and non-technical personnel **benefit from the use of an assay in which a signal means only a positive result because such results are not susceptible to misinterpretation, as may occur when the absence of signal indicates presence of analyte.**

(Col. 8, lines 19-29 (emphasis added).)

Thus, Fitzpatrick clearly teaches away from any results in which "the absence of signal indicates presence of analyte." This, however, is exactly the situation that occurs in the inversely proportional response of the claimed test zone. As the amount of analyte increases the strength of the signal decreases.

Moreover, Fitzpatrick is concerned only with the detection of "the presence [or absence] of an analyte in a sample" (Abstract) and nothing more. Fitzpatrick is completely silent as to any proportional response in the detection zone, as is required in the claimed reference zone. In the sole example in Fitzpatrick, the results are reported only as negative or positive for the detection of the analyte. (See Table 1 and col. 13, lines 21-48.)

Thus, Fitzpatrick does not disclose any proportional response in its detection zone and does not disclose any inversely proportional response in its trap zone. In fact, Fitzpatrick teaches a way from any inversely proportional response in its assays.

Accordingly, Fitzpatrick fails to teach at least two elements of the claimed invention, and therefore, the rejection fails to present a *prima facie* case for anticipation. For the foregoing reasons, withdrawal of the rejection is requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By 
Stephen J. Brown
Registration No.: 43,519
LERNER, DAVID, LITTENBERG,
KRUMLTZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicants

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